DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Notice of Approval of New Animal Drug Applications; Bacitracin; Lasalocid; Narasin; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that in 2002 it approved two original abbreviated new animal drug applications (ANADAs) for clindamycin hydrochloride oral dosage forms for dogs that were not the subject of final rules. Final rules were not published because the drug-specific section of the regulation did not require amendment.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that in 2002 it approved two original ANADAs for clindamycin hydrochloride oral dosage forms for dogs that were not the subject of final rules. Final rules were not published because 21 CFR 520.446 did not require amendment.

On June 6, 2001, FDA approved original ANADA 200–316 filed by Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Midlothian, VA 23113, for the veterinary prescription use of CLINTABS (clindamycin hydrochloride) Tablets in dogs. On June 14, 2002, FDA approved original

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ANADA 200–298 filed by Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, for the veterinary prescription use of Clindamycin Hydrochloride Capsules in dogs.

Both Delmarva Laboratories' CLINTABS Tablets and Phoenix Scientific's Clindamycin Hydrochloride Capsules are approved for the for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*, soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens* as generic copies of Pharmacia & Upjohn's ANTIROBE Capsules, approved under NADA 120–161. The necessary amendments adding these sponsors' drug label codes to 21 CFR 520.446 were made in a final rule (67 FR 54954, August 27, 2002) for the approval of an unrelated supplemental NADA for the pioneer product.

Freedom of information summaries containing approved product labeling may be seen in the Division of Dockets Management (HFA–305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/25/03
June 25, 2003.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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